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HEALTH

## FDA Bans Use Of Antibiotic In Poultry

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Fearing that the animal drug Baytril -- used to fight infections in chickens -- could pose health risks to humans, the Food and Drug Administration decided to ban its use in poultry.

The decision yesterday to restrict the Bayer AG antibiotic, which takes effect Sept. 12, marks the first time that the agency has ended the use of an animal drug because of worries that it could lead to antibiotic-resistant pathogens in humans. (Read the FDA statement.1)

"We made the determination that the drug was not safe," said Stephen Sundlof, director of the FDA's Center for Veterinary Medicine, which first asked for the drug's removal in 2000. The FDA's top official "has confirmed our original decision." The FDA's standard is that food from animals that have taken a particular drug must carry a "reasonable certainty of no harm," and the agency didn't feel that poultry treated with Baytril met that standard, he said.

A spokesman for Bayer's animal-health division said the ruling by FDA Commissioner Lester Crawford, a veterinarian, was "very disappointing" and the company hadn't yet decided whether it would appeal in federal court. Bayer has argued that its drug can't be tied to the rise of resistant bacteria.

The FDA's move highlights growing concern that animal bacteria transmitted to humans -- by means such as eating infected poultry -- may be resistant to antibiotics commonly prescribed to fight human illness.

The resistant bugs can arise in animals that are given antibiotics similar to human versions.

More broadly, infectious-disease specialists have warned that a slowdown in development of new classes of antibiotics for humans will leave doctors with few defenses against the rise of resistant pathogens.

Consumer groups applauded the FDA's announcement, which they said was an important step in the battle against resistant bacteria. The use of Baytril and similar drugs is "eroding, in a dramatic way, the effectiveness of human-use drugs," said Margaret Mellon, an official with the Union of Concerned Scientists. That group and others have called for the U.S. to take more steps to rein in the use of antibiotics in animals, and have backed a bill in Congress that would add restrictions.

Baytril is used to battle respiratory infections in turkeys and chickens, and it can be given to an entire flock through water if a few birds become sick. The FDA's move doesn't affect use of the drug in cows or pets such as dogs.

The FDA's concern is that use of Baytril is leading to a resistant form of the bacteria *Campylobacter*. *Campylobacter* causes food-borne gastrointestinal illness, and complications from it can include arthritis and rare blood infections, the FDA said. The agency has said that since Baytril's approval in 1996, a growing proportion of *Campylobacter* infections in humans have proved resistant to an important class of antibiotics called fluoroquinolones. Both Cipro, a popular human antibiotic, and Baytril are fluoroquinolones.

Use of Baytril had already been sharply curtailed, as many big producers had ceased using it. Perdue Farms Inc., for one, said it had never used the drug. Large fast-food chains such as McDonald's Corp. had already instructed their chicken suppliers not to use Baytril or other fluoroquinolones.

Abbott Laboratories withdrew a similar antibiotic from the market

voluntarily in 2000. But Bayer chose to fight the agency through an unusual administrative court process. The company won support from some members of Congress. But in March of last year, an administrative-law judge sided with the FDA's veterinary center. Now, the FDA's top official, Dr. Crawford, has also agreed.

Industry officials said the loss of the drug could leave few options to treat certain animal infections. Elizabeth Krushinskie, a vice president at the U.S. Poultry and Egg Association, an industry group, said Baytril was the most effective drug available to treat serious infections in poultry. The Animal Health Institute, which represents makers of animal drugs, said in a statement that it too was "disappointed."

Eric Gonder, a veterinarian with the turkey producer Goldsboro Milling Co. said the loss of Baytril will lead to a "small but aggravating increase in mortality" among the company's birds. In an average year, he said, about 5% of the company's eight million birds would receive the drug.

The U.S. has more lenient policies on the use of antibiotics in animals than a number of other countries. European countries have banned producers from using such drugs to promote growth if they are important for human use, and the European Union will require members to end the use of all antibiotics for animal growth by next year. The U.S. still allows such use.

In a report last year, the Government Accountability Office, the investigative arm of Congress, called for the U.S. to move more quickly in evaluating the potential risks posed by animal antibiotics that are also important products for human health. The FDA's Dr. Sundlof said the agency was in the process of reviewing the products, and "can only go as fast as the scientific information will allow us to."

In 2003, the FDA unveiled new standards for approval of animal drugs that factor in the potential risk of resistant bacteria arising in humans. Under those standards, Dr. Sundlof said, it is nearly impossible to get a new antibiotic approved as a growth promoter for animals.

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